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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,539	04/20/2004	Stanley L. Mills	MILS:002USC1	3891

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EXAMINER	
LAMPRECHT, JOEL	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,539	MILLS, STANLEY L.	
	Examiner	Art Unit	
	Joel M. Lamprecht	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-23,25-42 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-23,25-42 and 45* is/are rejected.

7)☒ Claim(s) *44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 45 is objected to because of the following informalities: Claim 45 is dependent from a canceled Claim, and is therefore improper. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3-23, and 25-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 2-38 of U.S. Patent No. 6,723,052 in view of Vitali et al (US 6,585,633 B2) in further view of McIntire et al (09/860,011 US 2002/0022781 A1). Claims 2-38 of US Patent No. 6,723,052 to the same inventive entity disclose all of the features of Claims 3-23, 25-28, 33-42 and 45. US Patent No. 6,723,052 does not disclose in the claims a medical device with

parabolic surface defining a body chamber and a radioisotopic component inside the body chamber and separated from the parabolic surface in at least one location by a gap, the medical device having a proximal and distal end and being adapted for implantation into a live body. Patent '052 also fails to Claim a device comprising a material selected from albumin, cellulose, gelatin and gut, comprising metal(s) such as titanium or having the device adapted to monitor the position of the radioisotopic component in a patient. Attention is then directed to the secondary reference by Vitali et al ('633) which discloses a device containing a material selected from albumin, cellulose, gelatin and gut as being a well-known spacer element component (Col 1 Line 50- Col 2 Line 11). Attention is also directed to the secondary reference by McIntire et al which discloses the design of a seed carrier comprising one or more metals including titanium [0004, 0008, 0029] and using the seeding device as a means for monitoring the positioning of the radioisotopic component in a patient with ultrasound [0012]. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the material designs of both McIntire et al and Vitali et al in US patent No. '052 for the purpose of furthering ultrasonic detection and providing a spacer element for the radioactive seeds there-disposed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3-12, 17-20, 25-26, 29, 33-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Vitali et al (US 6,585,633 B2). Vitali et al disclose a medical device comprising a parabolic surface defining a body chamber (Fig 1), a radioisotopic component (including 125I or 103PD) inside the body chamber and separated from the parabolic surface in at least one location by a gap (Fig 1-2), a number of parabolic surfaces each defining a body chamber and being able to contain spacer elements (Fig 11, 16) the medical device having a proximal and distal end and the device being adapted for implantation into a live body (Fig 31-34). Vitali et al also disclose a number of spacer elements along the device which may be made of polyglectin (Fig 26, Col 4 Line 5-35), body chambers connected to spacer elements that are connected to a second chamber of the device (Fig 25-26), the existence of a contrast material inside the body chamber (Col 4 Line 6-35),a docking guild near the proximal end of the device for accepting radioactive sources or spacers comprising a flexible joint (Fig 25-28, Col 5 Line 30 – Col 6 Line 20), a non-locking docking port, and discloses the use of catgut as a spacer element within the device (Col 1 Line 50-65). Vitali et al also disclose a device containing one or more voids, bubbles or channels including bubbles made of radioactive elements (Fig 2, Element 20), channels for the delivery of those said radioactive elements (Fig 14), and voids which may be filled with spacer elements (Fig 16, 15, and Figure 2 Element 18).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3-23, 25,26, and 25-26, 29-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitali et al in view of . Vitali et al disclose the invention as claimed including a medical device comprising a parabolic surface defining a body chamber (Fig 1), a radioisotopic component (including 125I or 103PD) inside the body chamber and separated from the parabolic surface in at least one location by a gap (Fig 1-2), a number of parabolic surfaces each defining a body chamber and being able to contain spacer elements (Fig 11, 16) the medical device having a proximal and distal end and the device being adapted for implantation into a live body (Fig 31-34). Vitali et al also disclose a number of spacer elements along the device which may be made of polyglectin (Fig 26, Col 4 Line 5-35), body chambers connected to spacer elements that are connected to a second chamber of the device (Fig 25-26), the existence of a contrast material inside the body chamber (Col 4 Line 6-35), a docking guild near the proximal end of the device for accepting radioactive sources or spacers comprising a flexible joint (Fig 25-28, Col 5 Line 30 – Col 6 Line 20), a non-locking docking port, and discloses the use of catgut as a spacer element within the device (Col 1 Line 50-65). Vitali et al also disclose a device containing one or more voids, bubbles or channels including bubbles made of radioactive elements (Fig 2, Element 20), channels for the

delivery of those said radioactive elements (Fig 14), and voids which may be filled with spacer elements (Fig 16, 15, and Figure 2 Element 18).

8. Vitali et al do not disclose a spacer element comprising a contrast material like silver, gold or tungsten or a device using LCP, metals such as titanium, and additionally does not mention specific monitoring of radioisotopic components in a patient; though the device is capable of such action, no reference is made to monitoring seed placement. Attention is then paid to the secondary reference by McIntire et al which discloses the use of a contrast material [0027], specifically silver for the carrier elements of the device for the purpose of making them x-ray detectable. McIntire et al also disclose the inclusion of titanium in the device [0008, and 0029] for the container materials. McIntire et al also provides reasoning and motivation for the inclusion of their device in the role of providing accurate position of the radioisotopic components in relation to the tissues of a patient [0009]. Finally McIntire disclose a number of additional polymers including Polypropylene, Polyethylene, and Polystyrene, all of which have specific gravities typically between .9 and 1.1 g/ml (From Modern Plastics Encyclopedia 99, p. B158 to-B216). It would have been obvious to one of ordinary skill in the art to have included the materials provided by McIntire et al with the brachytherapy seed delivery device of Vitali et al for the purpose of providing the most accurate and easily imaged brachytherapy system.

9. Claims 1, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitali et al in view of Coniglione (US 6,347,443 B2). Vitali et al disclose all that is listed above but fail to mention specifically using LCP as a polymer contained in the device.

Vitali et al do use a polymer but it is not liquid crystal polymer. Attention is then directed to the secondary reference by Coniglione in the same area of endeavor which describes LCP as an acceptable material along the lines of that which is used in Vitali et al for the construction of brachytherapy devices (Col 10 Line 25-50). It would have been obvious to one of ordinary skill in the art to have used the polymer disclosed by Coniglione in the brachytherapy device of Vitali et al for the purpose of providing a different nonabsorbable polymer for the construction of their brachytherapy device.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is included on the references cited sheet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML
5/10/07

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